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09/864,866	05/23/2001	R. Stephen Lloyd	265.0017 0101	2264

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/864,866

Applicant(s)

LLOYD ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 9, 10, 21, 22, 25, 26, 29, 30, 33, 34, 37, 38, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 9, 21, 25, 29, 33, 37 and 41 is/are allowed.
- 6) ☐ Claim(s) 10, 22, 26, 30, 34, 38 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: allowable subject matter indicated, interview summary enclosed.

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The Amendment and Response under 37 CFR §1.116 filed on July 2, 2003 as paper No. 20 is acknowledged. The amendments to the claims have been entered as requested. Claims 1-4, 11-12, 23-24, 27-28, 31-32, 35-36, 38-40, 43-44 are cancelled. Claims 21-22, 25-26, 29-30, 33-34, and 37-38 are amended. Claims 9-10, 21-22, 25-26, 29-30, 33-34, 37-38, 41-42 are pending and are the subject of this Office Action.

### **Detailed Action**

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

#### ***1. Rejoinder under 37 CFR § 1.121***

Claim 9-10, 41-42 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 21-22, 25-26, 29-30, 33-34 and 37-38, directed to the process or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 21-22, 25-26, 29-30, 33-34 and 37-38 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in Paper No. 8 is hereby withdrawn.

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2. Rejection under 35 USC section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10, 22, 26, 30, 34, 38, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 22, 26, 30, 34, 38 and 42 are confusing as claiming the same invention as that of claims 9, 21, 25, 29, 33, 37 and 41. The term "exogenous" recited in claim 10, 22, 26, 30, 34, 38 and 42 does not make the scope of the claims different from that of claim 9, 21, 25, 29, 33, 37 and 41. The reasons are as follows.

Claim 9, 21, 25, 29, 33, 37 and 41 are directed to a fusion DNA repair enzyme, or its method of use, wherein the enzyme consists of any of SEQ ID NO:41 (from chlorella virus), SEQ ID NO:42 (from bacteriophage T4) and SEQ ID NO:43 (from Micrococcus luteus) and a nuclear or mitochondrial targeting sequence. Claims 10, 22, 26, 30, 34, 38 and 42 are directed to a fusion DNA repair enzyme and its method of use, wherein the enzyme consists of any of SEQ ID NOs: 41, 42 and 43 and an exogenous nuclear or mitochondrial targeting sequence.

Viruses, phages and bacteria do not have nuclei and mitochondria. For that reason, they do not encode and express any nuclear or mitochondrial targeting

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sequence. SEQ ID NO: 41, 42, and 43 themselves do not comprise any nuclear or mitochondrial targeting domains. Thus, any nuclear or mitochondrial targeting sequence attached to any of SEQ ID NO: 41, 42 and 43 can only be exogenous. Therefore, the scope of the sets of claims 9, 21, 25, 29, 33, 37, 41 and 10, 22, 26, 30, 34, 38, 42 are the same. The examiner suggest cancellation of claims 10, 22, 26, 30, 34, 38, 42 10 and 42.

## *2.2. Scope of enablement*

Rejection of claims 1-4, 11-12 and 43-44 made under 35 U.S.C. 112, first paragraph made in the previous Office Action papers No. 19, 16 and 11 is withdrawn because the claims have been cancelled.

## **3. Conclusion**

Claims 9, 41 directed to the artifical DNA repair enzymes and their compositions, and claims 21, 25, 29, 33 and 37 directed to the methods of their use are allowed. Claims 10, 22, 26, 30, 34, 38 and 42 are rejected as duplicates of the allowed claims.

The following is the examier's reason for allowable subject matter. Applicants disclose novel arificial DNA repair enzymes consisting of well known viral and bacterial DNA repair enzymes of SEQ ID NO: 41, 42 and 43 and nuclear or mitochondrial targeting sequences. The invention is unobvious because any prior art suggests or provides motivation for combining the enzymes selected by Applicants with nuclear or mitochondrial targetting sequences.

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As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Patent Examiner

  
